

FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NANCY SULLIVAN and BURT SULLIVAN,

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS CORP.,
NOVARTIS CORP., NOVARTIS PHARMASTEIN
AG, and NOVARTIS AG,

Defendants.

Civ. No. 08-1091 (DRD)

OPINION

Appearances:

DOUGLAS & LONDON, P.C.

By: Michael A. London

111 John Street, Suite 1400

New York, NY 10038

BEHNKE, MARTIN & SCHULTE, L.L.C.

By: Richard Schulte

131 N. Ludlow Street, Suite 840

Dayton, OH 45402

Attorneys for Plaintiffs

HUGHES HUBBARD & REED LLP

By: Diane Lifton

101 Hudson Street, Suite 3601

Jersey City, NJ 07302

FAEGRE & BENSON

By: James A. O'Neal

2200 Wells Fargo Center

90 South Seventh Street

Minneapolis, MN 55402

Attorneys for Defendant Novartis Pharmaceuticals Corp.

DEBEVOISE, Senior District Judge

Plaintiffs, Nancy Sullivan and Burt Sullivan (the “Plaintiffs”), brought this action against Novartis Pharmaceuticals Corp., Novartis Corp., Novartis Pharmastein AG, and Novartis AG Novartis (the “Defendants”) in the New Jersey Superior Court (the “Superior Court”) with claims based upon products liability and consumer fraud under various New Jersey statutes and the New Jersey common law. Novartis filed a notice of removal (the “Notice”) in the United States District Court for the District of New Jersey, and Plaintiffs now bring this motion to remand the action to the Superior Court.

The facts of this young case are simple. According to the Complaint, Nancy Sullivan suffered injuries caused by her use of Novartis’s pharmaceutical product, Zelnorm® (“Zelnorm”), a drug used to treat irritable bowel syndrom. Plaintiffs state nine causes of action, two of which are relevant to this motion. Count three alleges failure to warn, pursuant to the New Jersey Products Liability Act (“NJPLA”), N.J.S.A. § 2A:58C-1 to -11. Count ten seeks punitive damages under the common law, the New Jersey Punitive Damages Act (“NJPDA”), N.J.S.A. §§ 2A:15-5.9 to -17, and the punitive damages provision of the NJPLA (N.J.S.A. § 2A:58C-5(c)).

After Plaintiffs filed the complaint, but before service could be affected, Novartis filed the Notice. Plaintiffs bring the instant motion on the grounds that the forum defendant rule precludes removal based upon diversity jurisdiction, and that the court lacks federal question jurisdiction because the action is attended by claims arising only from state law.

DISCUSSION

The court must resolve two separate issues in order to determine whether this case belongs in federal court. Novartis skillfully contends, first, that the case is removable based upon diversity jurisdiction because 28 U.S.C. § 1441(b)—which precludes removal in cases in which a forum defendant has been “properly joined and served”—should be interpreted according to its plain meaning, permitting removal in this case. Second, Novartis argues that Plaintiffs’ causes of action invoke substantial issues of federal law which support federal question jurisdiction.

Both of these arguments are unavailing.

I. Removal Generally

Congress has enacted a comprehensive statutory scheme addressing the removal of state court actions to federal court. See 28 U.S.C. §§ 1441-1452. Section 1441(a) provides that:

Except as otherwise expressly provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court . . . embracing the place where such action is pending.

In diversity cases, section 1441(b) imposes another condition above the requirements of original diversity jurisdiction, known as the “forum defendant rule.” Pursuant to section 1441(b), an action can be removed on the basis of diversity jurisdiction “only if none of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.” Thus, the forum defendant rule precludes removal based on diversity where a defendant is a citizen of the forum state--the state in which the plaintiff originally filed the case. See, e.g., Blackburn v. United Parcel Service, Inc., 179 F.3d 81 (3d Cir. 1999).

There is no similar provision restricting jurisdiction based upon questions of federal law,

and a case is removable—regardless of the forum residence of the defendant—if the court must resolve a substantial federal issue in order to dispose of the matter. See Grable & Sons Metal Prods., Inc. V. Darue Eng'g & Mfg., 545 U.S. 308 (2005).

II. Diversity Removal

In this case, the diversity of the parties and the amount in controversy are not disputed, so the court has original diversity jurisdiction over this case. At the time the Notice was filed, Novartis had not yet been properly joined and served in this action, and Novartis argues that, according to the plain meaning of section 1441(b), the forum defendant rule only applies to defendants that have been “properly joined and served.” Thus, Novartis contends that the removal was proper and should not be reversed.

Plaintiffs argue that applying the plain meaning of section 1441(b), and allowing Novartis—a forum defendant—to avoid the forum defendant rule merely because it had not yet been served at the time it filed the Notice, would amount to an absurd result, demonstrably at odds with Congressional intent. The court agrees.

In Fields v. Organon USA Inc., the court addressed precisely this issue, finding that the application of the plain meaning of section 1441(b) led to a result inconsistent with the intent of Congress. 2007 WL 4365312 (D.N.J. 2007). The court held that a defendant “is subject to the restrictions of section 1441(b) regardless of whether it had been properly served at the time of removal.” Id., at *3. See also DeAngelo-Shuayto v. Organon USA Inc., 2007 WL 4365311 (D.N.J. 2007) (Section 1441(b) applies even if the removing defendant has not been joined and served.).

Several district courts have come to the opposite conclusion, including this court. See, e.g., Chonko v. Comm’r of Soc. Sec., 2008 U.S. Dist. LEXIS 32867, at **12-13 (D.N.J. Apr. 22, 2008); Vongphakdy v. Astrue, 2008 U.S. Dist. LEXIS 18752, at *3 (E.D. Pa. Mar. 11, 2008); Frick v. Novartis Pharms. Corp., 2006 WL 454360 (D.N.J. 2006). In Frick, we found that the language of section 1441 was unambiguous, and that there was no clear indication that application of the plain meaning would result in an outcome demonstrably at odds with the will of provision’s drafters. Id., at **2-3

The various opinions applying the plain meaning of section 1441 have relied primarily on the principle of statutory construction which holds that courts should apply the plain meaning of a statute when the statutory language is clear and unambiguous. However, these courts, for the most part, have ignored a less often cited, but equally important, principle of statutory construction which holds that when the literal application of statutory language would either produce an outcome demonstrably at odds with the statute’s purpose or would result in an absurd outcome, a court must look beyond the plain meaning of the statutory language. Stephens v. Astrue, 2008 U.S. Dist. LEXIS 21429, at **8-9 (D. Md. Mar. 12, 2008); see also Green v. Bock Laundry Mach. Co., 490 U.S. 504, 527 (1989) (Scalia, J., concurring); In re Kaiser Aluminum Corp., 456 F.3d 328, 338 (3d Cir. 2006) (“A basic tenet of statutory construction is that courts should interpret a law to avoid absurd or bizarre results.”); United States v. Zats, 298 F.3d 182, 187 (3d Cir. 2002) (refusing to “read a text to produce absurd results [that are] plainly inconsistent with the drafters’ intentions”).

The literal application of § 1441(b) in this case would both produce bizarre results that Congress could not have intended, and results that are demonstrably at odds with the objectives

Congress did intend to effect. Therefore, the Court will look beyond the language of the statute in order to avoid an absurd and bizarre result, and in order to give effect to the purpose of the forum defendant rule and the “properly joined and served” language.

A. The Purpose of the “Properly Joined and Served” Language

The purpose of the “properly joined and served” language is to prevent the abuse of the forum defendant rule by improper joinder (formerly referred to as fraudulent joinder)¹. Brown v. Organon USA Inc., 2008 WL 2625355, at *7 (D.N.J.); Allen v. GlaxoSmithKline PLC, 2008 WL 2247067, at *6 (E.D.Pa.); Brown v. Organon Intern. Inc., 2008 WL 2833294, at **4-5 (D.N.J.); DeAngelo-Shuayto, 2007 WL 4365311, at *1; Stan Winston Creatures, Inc. v. Toys “R” US, Inc., 314 F.Supp.2d 177, 181 (S.D.N.Y.); Holmstrom v. Harad, No. 05-2714, 2005 WL 1950672, at *2 (N.D.Ill.); Aredia and Zometa Products Liability Litigation, No. 07-0779, 2007 WL 2905247, at *2 (M.D.Tenn.).²

Despite the court’s recent conclusion that the language of section 1441(b) is unambiguous, and that resort to legislative history was, therefore, unnecessary, see Frick, 2006 WL 454360 at **2-3, an analysis of the issues presented in this case cannot avoid a discussion of the purpose of section 1441(b). In determining the purpose of section 1441(b), we look to the relevant legislative history, and the structure and historical context of the statute. U.S. v. E.I.

¹Improper joinder is the practice of naming a forum-resident entity as a defendant solely to prevent an action from being removed to federal court (either by implicating the forum defendant rule, or by destroying diversity jurisdiction), see, for example, Allen v. Bongiovi, 2007 WL 869535, at *2 (D.N.J. 2007).

²For a fair summary of the development of case precedent concerning the forum defendant rule, see John P. Lavelle, Jr. & Erin E. Kepplinger, Removal Prior to Service: a New Wrinkle or a Dead End?, 75 Def.C.J. 177 (Winter 2008).

Dupont De Nemours and Co. Inc., 432 F.3d 161, 169 (3d Cir. 2005) (citing Gen. Dynamics Land Sys. v. Cline, 540 U.S. 581, 600 (2004))

The removal doctrine has been a part of American jurisprudence since the execution of the Judiciary Act of 1789. See Wisconsin Dep't of Corrections v. Schacht, 524 U.S. 381, 386 (1998) (citing 1 Stat. 72, 79-80). The original removal provision did not include the “properly joined and served” limitation, 1 Stat. 72, 79-80, which Congress made a part of Title 28 in the year 1948, see 28 U.S.C. § 114 (1940); 28 U.S.C. § 1441(b) (1948).

The court has conducted a thorough examination of the published legislative history regarding the 1948 changes to Title 28, including review of all legislative materials available in the Third Circuit libraries in Newark and Philadelphia and the DC Circuit library in Washington. The court has been able to locate neither a specific statement from Congress nor from the advisory Committee on Revision of the Judicial Code (the “Committee”), regarding the addition of the “properly joined and served” language. See 28 U.S.C. § 1441 (1948) reviser’s notes; H.R. Rep. No. 80-308 (1947), as reprinted in 1948 U.S.C.C.S., Special Pamphlet: Title 28 at 1692; S. Rep. No. 80-1559 (1948), as reprinted in 1948 U.S.C.C.S. Special Pamphlet: Title 28, 1675; Letter from Hon. Albert B. Maris, Circuit Judge, United States Court of Appeals for the Third Circuit, and Chair of the Committee, to Mildrim Thompson, Jr., Esq. (May 10, 1946). Further, the Circuit Courts have provided little guidance on the statutory interpretation of the “properly joined and served” language of section 1441(b), owing to the fact that the orders of district courts made pursuant to section 1441, generally are not reviewable. Cook v. Wikler, 320 F.3d 431, 438-39 (3d Cir. 2003).

Despite the lack of guidance, the purpose of the “properly joined and served” requirement of section 1441(b) is abundantly clear in light of the historical development of the policy of the remand provisions, the practical application of the “joined and served” provision by district courts in recent decades, and common sense.

The Supreme Court first addressed the service issue in 1939 in Pullman Co. v. Jenkins, 305 U.S. 534, 541. In Pullman, the Court affirmed the then-standing rule that a non-resident defendant could not remove an action in which a forum defendant was named, even if the forum defendant had not been served with process. Although this left open a window for the improper joinder of a forum defendant, the Court explained that improper joinder could be prevented by a demonstration that “the resident defendant has not been joined in good faith and for that reason should not be considered in determining the right to remove.” Id. The competing policy goals which the Court had to balance were whether “the non-resident defendant may be prejudiced because his co-defendant may not [ever] be served”, and preventing the non-resident defendant from seizing the “opportunity to remove the cause before service upon the resident co-defendant is effected.” Id. The Court choose to further the latter policy, refusing to allow removal merely because the forum defendant had yet to be served. Id.

By 1948, it was clear that the troublesome issue of improper joinder required a less muddled solution than merely examining a plaintiff’s good faith in naming various forum defendants. Congress added the “properly joined and served” requirement in order to prevent a plaintiff from blocking removal by joining as a defendant a resident party against whom it does not intend to proceed, and whom it does not even serve. Stan Winston Creatures, 314 F.Supp.2d at 181; Holmstrom, 2005 WL 1950672, at *2; and see, e.g., Cucci v. Edwards, 510 F.Supp.2d

479 (C.D.Cal. 2007) (removal permitted despite forum residence of an unserved defendant).

There is no evidence to support the notion that Congress intended to reverse the Pullman Court’s prophetic—and, at the time, largely theoretical--dictum concerning preventing the defendant from seizing the “opportunity to remove the cause before service upon the resident co-defendant is effected.” Id. Congress appears to have added the language only to prevent the then-concrete and pervasive problem of improper joinder. Indeed, it is inconceivable that Congress, in adding the “properly joined and served” language, intended to create an arbitrary means for a forum defendant to avoid the forum defendant rule simply by filing a notice of removal before the plaintiff is able to effect process. See Fields, 2007 WL 4365312.

Defendants argue, unavailingly, that the addition of the language signaled an intention by Congress to “narrow this exception to the statutory right of removal.” There is nothing in the history of the removal doctrine, legislative or otherwise, which even suggests why Congress would have intended to limit the forum defendant rule. In fact, Congress has never deviated from the “fundamental precept of the American court system” that federal jurisdiction is very limited. New Rock Asset Partners, L.P. v. Preferred Entity Advancements, Inc., 101 F.3d 1492, 1502 (3d Cir. 1996) (citing Owen Equip. & Erection Co. v. Kroger, 437 U.S. 365, 374 (1978)).

Instead, the fact that the legislative history is all but silent on the issue suggests that Congress did not intend to address a novel concern or fundamentally change the nature of, or narrow the scope of the rule. Indeed, the very lack of discussion in the legislative history strongly suggests that Congress intended nothing more than to bolster the already existing efforts of lower federal courts to prevent improper joinder.

Defendants further argue, quoting City of Ann Arbor Employees' Retirement System v.

Gecht, that:

if Congress had wanted to ensure that removal would not be appropriate until it was clear that Plaintiff was trying to prevent removal by speciously naming resident defendants, Congress could have provided that no removal petition could be filed until one or more nonresident defendant had been joined and served. The statute also could have been written to give a plaintiff, e.g., 30 or 60 days to effect service before permitting a defendant to remove.

2007 WL 760568, at *9 (N.D.Cal.). This is simply not true since, as discussed in Part B, infra,

Congress could not possibly have anticipated the tremendous loophole that would one day manifest from technology enabling forum defendants to circumvent the forum defendant rule by, inter alia, electronically monitoring state court dockets. Thus, Congress would have had no thought to wording the statute with this modern problem in mind.

B. A Plain Meaning Application Would Lead to Bizarre Results that Congress Could Not Have Intended.

Novartis's contention that removability should depend on the timing of service of process is absurd on its face, see Oxendine v. Merck and Co., Inc., 236 F.Supp.2d 517, 526 (D.Md. 2002) (“removability can not rationally turn on the timing or sequence of service of process”), and could not have been intended by Congress. It is beyond dispute that the Eightieth Congress, sitting in 1948, could not possibly have foreseen the development of electronic docket monitoring and the technologically-advanced facts of this opinion. As a matter of common sense, the court is confident, beyond any doubt, that Congress did not add the “properly joined and served” language in order to reward defendants for conducting and winning a race, which

serves no conceivable public policy goal, to file a notice of removal before the plaintiffs can serve process. The court cannot imagine what Congressional policy goal—and Novartis, here, has offered no example—which would be furthered by rewarding defendants for such gamesmanship. As described, supra, the Pullman Court, addressing a different nuance of the same issue, declared that such a race to remove was not to be encouraged. Id., 305 U.S. at 541. As another district court held, in Oxendine v. Merck and Co., Inc., “removability cannot rationally turn on the timing or sequence of service of process.” 236 F.Supp.2d 517, 526 (D.Md. 2002). The court, here, agrees.

Thus, the court deems that such a result is bizarre or absurd, and even in the absence of any substantially helpful legislative materials, is determinative that section 1441(b) must not be read literally in this instance.

In reaching its decision, the court has reviewed the related opinions of other district courts discussing the “properly joined and served” language of section 1441.³ Many of these courts have focused on whether to follow the decision of the Northern District of Illinois in Holmstrom v. Harad, which this court now finds persuasive. 2005 WL 1950672 (N.D.Ill. Aug. 11, 2005). Holmstrom involved a shareholder derivative action originally filed in Illinois state court with twenty-eight named defendants, including two Illinois residents. Id., at * 1. One of the

³Vivas v. Boeing Co., 486 F.Supp.2d 726 (N.D.Ill. 2007); Ripley v. Eon Labs Inc., Civ. Action No. 07-912, 2007 WL 2406806 (D.N.J. Aug. 16, 2007); Waldon v. Novartis Pharms. Corp., No. C07-01988 MJJ, 2007 WL 1747128 (N.D. Cal. June 18, 2007); Thomson v. Novartis Pharms. Corp., Civ. No. 06-6280(JBS), 2007 WL 1521138 (D.N.J. May 22, 2007); City of Ann Arbor Employees' Ret. Sys. v. Gecht, No. C-06-7453 EMC. Docket No. 7, 2007 WL 760568 (N.D.Cal. March 9, 2007); Massey v. Cassens & Sons, Inc., No. 05-CV-598-DRH, 2006 WL 381943 (S.D.Ill. Feb. 16, 2006); Maitra v. Mitsubishi Heavy Indus., Ltd., No. CIV.A. SA01CA0209FBNN, 2002 WL 1491855 (W.D.Tex. March 29, 2002).

defendants, a citizen of Ohio, removed the action to federal district court before any of the defendants had been served. Id. The Holmstrom court noted that under the plain language of § 1441(b), an unserved forum defendant does not bar removal, but the court nevertheless denied removal, reasoning that where no defendant has been served, the “policy of the ‘joined and served’ requirement is not implicated.” Id., at *2. Most district courts, following Holmstrom, have held that a literal reading in this context would be absurd. In light of the purpose of the removal statute generally, and the “properly joined and served” language specifically, as described, supra, at part A, the court agrees.

Therefore, the court will look past the plain meaning of § 1441(b) in order to avoid an absurd and bizarre result which Congress could not have intended.

C. A Plain Meaning Application Would Lead to Results Demonstrably at Odds with Congressional Intent.

The result of blindly applying the plain “properly joined and served” language of section 1441(b) is to eviscerate the purpose of the forum defendant rule. See Lively v. Wild Oats Mkts., Inc., 456 F.3d 933, 939 (9th Cir.2006) (the forum defendant rule limits removal to cases in which there might be a theoretical need to “protect out-of-state defendants from possible prejudices in state court”). Reading the “properly joined and served” language literally in this context would damage the plaintiff’s rightful position as “master of his or her complaint,” see United Jersey Banks v. Parell, 783 F.2d 360, 368 (3d Cir. 1986) (citing Hunter v. United Van Lines, 746 F.2d 635, 640 (9th Cir. 1984), cert. denied, 474 U.S. 863 (1985)), creating a procedural anomaly whereby defendants could always avoid the imposition of the forum defendant rule so long as

they monitor the state docket and remove the action to federal court before the plaintiff can effect service of process.⁴ Fields, 2007 WL 4365312, at *5.

Moreover, given that the purpose of the “properly joined and served” language is to prevent one form of gamesmanship—improper joinder--the court finds that allowing defendants to engage another type of gamesmanship—a hasty filing of a notice of removal--is demonstrably at odds with Congressional intent.

Therefore, the court will look past the plain meaning of § 1441(b) in order to give effect to the purpose of the forum defendant rule and its “properly joined and served” language.

III. Federal Question Removal

Relying on Grable, Novartis contends that although Plaintiffs do not allege any federal cause of action in the complaint, the case is subject to the court’s jurisdiction because the disposition of Plaintiffs’ claims requires resolution of substantial federal issues.⁵ In Grable, the Supreme Court re-articulated “the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law” so long as such jurisdiction does not disturb “any congressionally approved balance of

⁴In some state court systems, defendants easily win the race to remove--before being served by the plaintiff--because plaintiffs cannot serve defendant before receiving a state track assignment number. This assignment can take over a week from the time the plaintiff files suit, during which time the defendant can learn of the action and remove it to federal court. See Thomson v. Novartis Pharm., Corp., Civ. No. 06-6280 (JBS), 2007 WL 1521138, *3 n. 4 (D.N.J. May 22, 2007).

⁵Novartis also relies upon an FDA memorandum regarding the approval of product labeling, conflicting state law claims related to the adequacy of prescription drug warnings, and preemption arguments. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed.Reg. 3922, 3934, 3935 (Jan. 24, 2006).

federal and state judicial responsibilities.” 545 U.S. at 312, 314.

Novartis argues that two of Plaintiffs’ claims support removal: (1) the cause of action for failure to warn, pursuant to the NJPLA (the “Failure to Warn Claim”), and (2) the cause of action for punitive damages, specifically as alleged pursuant to the punitive damages provision of the NJPLA (the “Punitive Damages Claim”). Novartis contends that the Failure to Warn Claim necessarily requires that the court address “a number of disputed and substantial federal questions regarding the proper interpretation of [the] FDA’s regulations on labeling, the FDA’s role in the regulation of prescription pharmaceuticals, and ultimately whether plaintiffs’ . . . claims impermissibly conflict with FDA regulatory decisions . . .” Regarding the Punitive Damages Claim, Novartis contends the NJPLA incorporates federal law by requiring that plaintiffs prove “fraud-on-the-FDA” as part of their claims.

Plaintiffs argue that the removal was improper since their complaint filed in state court is based exclusively upon state law claims. They argue that Novartis may not remove the case on the basis of what is, in effect, a federal defense of preemption, i.e., Novartis’s contention that Congress has occupied the field of drug regulation. Specifically, they contend that the causes of action do not require that Plaintiffs prove that the Defendants violated any portion of federal law as an element of, or prerequisite to, any of their claims, and that even if federal issues are involved, such issues are not substantial.

In determining whether a case arises under federal law, courts are instructed to look to the plaintiff’s “well-pleaded complaint.” U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002) (citing Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 808 (1986)). It is not

enough that a federal question is or may be raised as a defense. Id. The controversy must be disclosed upon the face of the complaint, unaided by the answer or by the petition for removal.” Id. (quoting Gully v. First Nat'l Bank in Meridian, 299 U.S. 109, 113 (1936)). In addition to jurisdiction based upon causes of action arising from federal statutes and the U.S. Constitution, the Supreme Court has long held that 28 U.S.C. 1331 includes a preemption form of federal question jurisdiction for purposes of removal of state law claims involving significant federal issues. Grable, 545 U.S. at 312 (citing Hopkins v. Walker, 244 U.S. 486, 490-491 (1917)). “The state suit need not invoke a federal law in order to ‘arise under’ it for removal purposes. It is sufficient that the merits of the litigation turn on a substantial federal issue that is ‘an element, and an essential one, of the plaintiff’s cause of action.’” U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002) (quoting Gully v. First Nat'l Bank in Meridian, 299 U.S. 109, 112 (1936)).

The Supreme Court has not stated a “‘single, precise, all-embracing’ test for jurisdiction over federal issues embedded in state-law claims between nondiverse parties.” Grable, 545 U.S. at 314 (quoting Christianson v. Colt Industries Operating Corp., 486 U.S. 800, 821 (1988) (STEVENS, J., concurring)). The Court of Appeals has yet to address the question of whether the particular New Jersey causes of action before the court may raise substantial federal issues; however, five district court opinions have addressed these NJPLA claims, each finding that the NJPLA causes of action belong in state court because their disposition does not require the resolution of any substantial federal issues, or because a finding of federal jurisdiction would upset the federal-state workload balance. See Fields, 2007 WL 4365312; Brown v. Organon Intern. Inc., 2008 WL 2833294 (D.N.J. 2008); DeAngelo-Shuayto v. Organon USA Inc., 2007

WL 4365311 (D.N.J. 2007); Von Essen v. C.R. Bard, Inc., 2007 WL 2086483 (D.N.J. 2007); In re Aredia and Zometa Products Liability Litigation, 2007 WL 649266 (M.D.Tenn. 2007).

Neither of the claims at issue affords a basis for finding both that Plaintiffs' "right to relief under state law requires resolution of a substantial question of federal law in dispute between the parties," and that the federal-state judicial balance would not be upset by a finding of federal jurisdiction. Franchise Tax Board v. Construction Laborers Vacation Trust, 463 U.S. 1, 13 (1983).

A. The Failure to Warn Claim

The United States District Court for the Middle District of Tennessee held, in Aredia, that the plaintiff's causes of action based upon the NJPLA—the same Failure to Warn Claims raised in the instant case--were not subject to federal jurisdiction. 2007 WL 649266. Finding the Tennessee federal court's analysis thorough and persuasive, the court adopts the conclusions reached in Aredia regarding the NJPLA failure to warn claims, and much of the reasoning that follows is borrowed from court's opinion in Aredia.

The Supreme Court has decided two cases which are particularly pertinent to the court's analysis. In Merrell Dow, the Court decided a question very similar to the one before the court today, finding that a state court negligence action against a drug manufacturer, resting in part on the allegation that the defendant drug company had violated a federal misbranding prohibition, did not present a federal question, so that removal of the action to federal court was improper. 478 U.S. at 804. The Court held that "a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private,

federal cause of action for the violation, does not state a claim ‘arising under’” section 1331. Id. at 817.

Later, in Grable, the Court held that an action based upon a state law quiet title claim raised substantial federal issues which supported the removal of a case, even though Congress had not created any private, federal cause of action which would have entitled plaintiff to relief. 545 U.S. at 309.

In clarifying its earlier opinion, the Grable Court held that Merrell Dow “should be read in its entirety as treating the absence of [a parallel federal cause of action] as evidence relevant to, but not dispositive of, the ‘sensitive judgements about congressional intent’ required by § 1331.” 545 U.S. at 309 (citing Merrell Dow, 478 U.S. at 810).⁶ In other words, the fact that Congress has not created a federal cause of action, does *not* necessarily deprive the district court of jurisdiction. 545 U.S. at 309. The Court cautioned, however, that “[b]ecause arising-under jurisdiction to hear a state law claim always raises the possibility of upsetting the state-federal line drawn (or at least assumed) by Congress, the presence of a disputed federal issue and the ostensible importance of a federal forum are never necessarily dispositive; there must always be an assessment of any disruptive portent in exercising federal jurisdiction.” Id. at 314.⁷ The

⁶ The Third Circuit Court of Appeals had previously reached the same conclusion in U.S. Express Lines Ltd. v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002).

⁷When the court concludes that Congress has decided not to provide a particular federal remedy, the court is not free to “supplement” that decision in a way that makes it “meaningless.” Cf. Mobil Oil Corp. v. Higginbotham, 436 U.S. 618, 625 (1978) (When Congress “does speak directly to a question, the courts are not free to ‘supplement’ Congress’ answer so thoroughly that the Act becomes meaningless”). See also California v. Sierra Club, 451 U.S., at 297, 101 S.Ct., at 1781 (“The federal judiciary will not engraft a remedy on a statute, no matter how salutary,

question to ask is: “Does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities?” Id.

Significantly, the Grable Court did *not* overrule Merrell Dow, and, in fact, cited Merrell Dow with approval, stating that Merrell Dow's “analysis thus fits within the framework of examining the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts.” Id. at 319. The case before the court today involves claims similar to those Merrell Dow, in terms of the absence of any parallel federal cause of action, the significance of the federal components (or lack thereof), and the likelihood that opening the federal forum would significantly alter the state-federal workload balance.

In Merrell Dow, the Court held that a general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would have “heralded a potentially enormous shift of traditionally state cases into federal courts.” Grable, 545 U.S. at 319 (citing Merrell Dow, 478 U.S. at 811-12). The Grable Court distinguished Merrell Dow by examining the enormous difference in the impact of opening the federal forum to the respective causes of action would have on the state-federal court balance. Grable, 545 U.S. at 318-19. The Court explained that “if the federal labeling standard [addressed in Merrell Dow] without a cause of action could get a state claim into federal court, so could any other federal standards without causes of action. And that would mean an enormous number of cases.” Grable, 545 U.S. at 318.

that Congress did not intend to provide”).

By contrast, the Grable Court addressed a state law quiet title action, and found that “[a]lthough Congress . . . indicated ambivalence in this case by providing no private right of action to Grable, it is the rare state quiet title action that involves contested issues of federal law . . . [c]onsequently, jurisdiction over actions like Grable's would not materially affect, or threaten to affect, the normal currents of litigation.” Id. at 319.

In the instant case, the court has reviewed Novartis's list of potential federal issues and finds that, given the Supreme Court's holdings in Grable and Merrell Dow, they are not substantial to the extent that the Plaintiffs' case rests on the resolution of these issues. In spite of Novartis's blanket assertions to the contrary, Plaintiffs' stated causes of action do not require proof of violation of federal law as an essential element to recovery, Grable, 545 U.S. at 319, and merely constitute potential defenses to Plaintiffs' claims. The court believes these issues, if they arise, could be properly handled by the state court as part of Plaintiffs' state law claims.

Moreover, even if these claims raised substantial federal issues, given the “potentially enormous shift of traditionally state cases into federal courts” which could result from opening the federal forum to these claims, the court finds that any possible federal issues related to Plaintiffs' failure to warn claims do not rise to the kind of adjudication for which federal jurisdiction would serve congressional purposes and the federal system. Grable, 545 U.S. at 319 (citing Merrell Dow, 478 U.S. at 811-812).

Considering that the federal issues potentially raised in the instant case are no more substantial than those raised in Merrell Dow, and considering the Grable Court's praise for Merrell Dow's effect of protecting the federal system from a significant disturbance in the

federal-state workload balance, the court must not exercise jurisdiction over the instant claim for Failure to Warn.

B. The Punitive Damages Claim

Sullivan's punitive damages claims are based upon a provision of the New Jersey Product Liability Act that prohibits the award of punitive damages if the litigated drug or medical device was subject to premarket approval by the FDA unless "the product manufacturer knowingly withheld or misrepresented information" in violation of the FDA's regulations. N.J.S.A. § 2A:58C-5(c). Thus, Novartis argues, a "fraud-on-the-FDA claim" is necessarily embedded in Plaintiff's punitive damages claim and, pursuant to the Supreme Court's holding in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 353 (2001), such a claim "is inherently federal in character." Like the court in Fields, the court agrees with Novartis that state courts probably cannot step into the shoes of the FDA to determine whether a fraud on the FDA has been committed, but Plaintiffs' claims for punitive damages nonetheless do not warrant federal jurisdiction. Fields, 2007 WL 4365312, at *6.

While Buckman dictates that state fraud-on-the-FDA claims are preempted, "Buckman does not make any holding with regard to the existence of federal question jurisdiction over a case by virtue of a state law claim that incorporates federal law as setting forth the standard of offending conduct." DeAngelo-Shuayto, 2007 WL 4365311, at *7. The issue in this case is whether Plaintiffs' claims arise under federal law, not whether there is preemption under Buckman. In a similar case, Judge Chesler concluded that "[a] state law cause of action does not give rise to a substantial and disputed question of federal law simply because it is predicated

on conduct regulated by federal law.’ ” Id. (quoting Hirschbach v. NVE Bank, 496 F.Supp.2d 451, 455 (D.N.J.2007)).

Novartis argues that Plaintiffs' claim for punitive damages raises a substantial federal question because New Jersey's punitive damages statute incorporates federal law by providing for a “fraud-on-the-FDA” exception. Novartis contends that the Plaintiffs are barred from recovering punitive damage unless the Plaintiffs establish that Novartis “knowingly withheld or misrepresented” material and relevant information to the FDA, which would require Plaintiffs to establish that Novartis violated federal law in its submission of materials to the FDA.

Plaintiffs respond that their claims do not turn on a “fraud on the FDA claim,” but rather that New Jersey law sets a standard whereby a plaintiff need only show that the drug company withheld information that was material and relevant to the harm in question in order to support a punitive damages claim. Plaintiffs assert that no inquiry into FDA procedures or analysis or speculation as to what the FDA would have done with the information is necessary.

The Supreme Court has expressly considered the question of a state common law fraud-on-the-FDA tort claim and has found that it is impliedly preempted by the FDCA. Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). Buckman was a diversity case where the plaintiffs' theory of liability was that but-for the defendant's fraudulent statements to the FDA, the bone screws would have never received FDA approval, and the plaintiffs would not have been injured. Id. The Supreme Court found that, “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’” Id. at 347 (citing Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947)). Further, the Supreme Court

found that state law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgement and objectives. Id. at 350. The Supreme Court was concerned that “complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants-burdens not contemplated by Congress in enacting the FDCA . . . ” Id. Further, fraud-on-the-FDA claims “would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants or needs, resulting in additional burdens on the FDA's evaluation of an application” causing delays and impeding competition. Id. at 351.

In contrast to Buckman, the present case does not involve a claim of fraud-on-the-FDA but instead involves a state statute which immunizes drug manufacturers from punitive damage liability unless the plaintiff can prove fraud-on-the-FDA. Stated differently, Buckman involved a specific cause of action for fraud-on-the-FDA, whereas the instant Plaintiffs must prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under New Jersey law.

In Garcia v. Wyeth-Ayerst, a diversity action, the plaintiff brought a products liability action against a drug manufacturer seeking punitive damages. 385 F.3d 961 (2004). Michigan, like New Jersey, immunizes drug manufacturers from punitive damage liability in actions based on injuries from FDA-approved drugs absent a showing that the drug manufacturers secured FDA approval through fraud. The Sixth Circuit held that the distinction between a plaintiff who brought a direct cause of action for fraud on the FDA and a plaintiff who had to prove fraud on the FDA merely as a prerequisite to obtaining punitive damages under Michigan law was

immaterial in light of Buckman. Id. at 965-66. The Sixth Circuit held that regardless of whether a plaintiff is required to prove fraud on the FDA as a cause of action unto itself or simply as a prerequisite in a punitive damages action, “such a state court proceeding would raise the same inter-branch-meddling concerns that animated Buckman.” Id. at 966 (citing Buckman, 531 U.S. at 351).

In Kobar v. Novartis Corporation, the same issue was presented as in Garcia, in the context of a similar Arizona statute, on a motion for partial summary judgment on the issue of punitive damages. 378 F.Supp.2d 1166 (2005). There, the Plaintiff made the same argument as the Plaintiffs in the instant case, i.e., that she did not have to prove fraud-on-the-FDA but rather merely that the drug manufacturer withheld “material and relevant” information from the FDA during the approval process. Id. at 1172-73. However, the Kobar Court was not persuaded by the distinction, finding that “[b]oth common law fraud on the FDA claim and an immunity statute that requires a plaintiff to prove fraud on the FDA in order to collect punitive damages place state courts, as finders of fact, in the uncomfortable and difficult position of having to answer the question of what role, if any, the allegedly withheld information would have played in the FDA's complicated approval process.” Id. The Kobar Court further stated that the “FDA is equally empowered to police and deter fraud with respect to the drug approval process ... [and] the FDA has the authority to request additional information from a drug manufacturer, investigate suspected fraud, seek injunctive relief and civil penalties and pursue criminal prosecutions.” Id. at 1173. As in Garcia, the Kobar Court found that severing the fraud exceptions from the rest of the Arizona statute would still allow a plaintiff to obtain punitive damages so long as the FDA itself made a finding that it has been defrauded by the drug

manufacturer. Id. at 1176.

Neither Buckman, Garcia nor Kobar address whether the request for punitive damages when there is a fraud-on-the-FDA exception is a substantial issue which warrants removal to federal court. It is important to again note that a case may not be removed to federal court on a the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties concede that the federal defense is the only question truly at issue. Caterpillar Inc. v. Williams, 482 U.S. 386, 107 S.Ct. 2425, 96 L.Ed.2d 318 (1987). Baldwin v. Pirelli Armstrong Tire Corp., 927 F.Supp. 1046 (M.D.Tenn.1996).

Plaintiffs' claims for punitive damages may not require the New Jersey state court to find fraud-on-the-FDA, and thus, no substantial federal issue is present which warrants federal jurisdiction. Rather, Novartis may present a defense to the New Jersey state court, similar to the defendants in Garcia and Kobar, that the portion of the New Jersey statute which requires Plaintiffs to demonstrate that “the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question” is preempted and can only be satisfied by an FDA finding of fraud. As noted above, this federal preemption defense is not sufficient to remove a state law complaint to federal court.

Novartis will have an opportunity to present its preemption arguments as a defense in the New Jersey superior court. Although Novartis argues that New Jersey state courts have been unwilling to find that these laws are preempted, errors in the state court must be addressed

through the appropriate appellate channels, and not by expanding federal jurisdiction.

In any event, even if these claims raise substantial federal issues, opening the federal forum to these claims would cause a “potentially enormous shift of traditionally state cases into federal courts,” and the court finds that any possible federal issues related to the Punitive Damages Claims do not rise to the kind of adjudication for which federal jurisdiction would serve congressional purposes and the federal system. Grable, 545 U.S. at 319 (citing Merrell Dow, 478 U.S. at 811-812). In particular, opening the federal forum in this case would have the effect of shifting to federal court an enormous volume of state law claims in which manufacturers are protected from punitive damages so long as they have made no misrepresentations to the FDA. The court finds that Congress has given no indication of an intention to effect the same.

Therefore, the court finds that neither the Failure to Warn Claim nor the Punitive Damages Claims involve substantial federal questions for which the federal forum must be opened, and the case is not removable on grounds of federal question jurisdiction.

CONCLUSION

_____ For all the reasons stated above, Plaintiffs' motion to remand will be granted.⁸

s/ Dickinson R. Debevoise

Dickinson R. Debevoise, U.S.S.D.J.

Dated: September 9, 2008

⁸Novartis suggests that, if the court follows the opinion in Aredia, the court should retain and dismiss the preempted causes of action, and remand the remaining claims to the Superior Court. The court finds that, though some of the claims are preempted by federal law, the court does not have jurisdiction over any of the claims, and the entire case belongs in the Superior Court.